REMARKS

Before responding to the latest official action in this case, a brief review of this prosecution history is deemed to be warranted. An initial restriction requirement issued on October 20, 2006, in this case. Applicant responded on November 14, 2006, but the Examiner initially took the position in an action of March 22, 2007, that applicant's response to the restriction requirement of October 20, 2006, was not compliant. After a telephone interview, however, this position was withdrawn. In any event, an official action on the merits then issued on June 20, 2007. In that action, certain claims were rejected as being anticipated, and a number of claims were said to be in condition for allowance. Applicant then responded on September 7, 2007, and another notice of noncompliant amendment was then received, based on the nature of the claim status identifiers. Applicant then responded by once again filing that amendment with the suggested corrections.

In the latest official action, however, for the first time, the Examiner now rejects the Abstract, and has withdrawn the indication of allowability from the prior action. This is said to be based upon a new interpretation of the Fields *et al.* patent, which had previously been applied against the claims. Furthermore, this action now includes 13 pages of additional rejections, which will now be dealt with. Suffice it to say, however, that after a period of almost six years from the filing date of this application, it appears that, at least from the Examiner's perspective, a true first action on the merits has now been received. This is not believed to be the epitome of efficient examination, and applicant now strenuously appeals to the Examiner to carefully consider applicant's responses and to hopefully concede that the Examiner's ultimate position with respect to the nature of the prior art against these claims has now been set forth.

Turning to the official action itself, the Examiner first contends that claim 63 recites "said medical gases" but that there is insufficient antecedent basis therefor. However, in view of the above-noted amendments to claim 63, it is submitted that this rejection has now been obviated. Furthermore, with respect to claim 66, this claim had depended from canceled claim 60, and has therefore been amended to correctly depend from claim 59 as interpreted by the Examiner.

Claims 59, 66-68, 71, 154-156, and 159 have been rejected as being anticipated by Fields *et al.* under 35 U.S.C. § 102(b).

With respect to claim 59, the Examiner contends that Fields *et al.* discloses the claimed apparatus with an upper portion (head 10) connected with a lower portion (sleeve 50) in a configuration in which the housing is closed, citing Fig. 2 thereof. Compressed gas cartridge (container 60) is disposed within the housing and is said to contain a medical gas for normal respiration (col.1 ll.1-6), patient supply means (nozzle 100)(col.2 ll.34-44), a cassette (housing 30)(Fig. 1, col.2 ll.17-23), and mounting means including first acceptance means (rubber washer 26) compatible with a second acceptance means (flange 48) on the cassette for mounting the cassette within the housing (col.2 ll.17-21). The compressed gas cartridge is said to be mounted on the cassette (Fig. 2, col.2 ll.24-29), and the compressed gas cartridge is said to have a size and configuration whereby the housing can be closed with the cartridge disposed within the housing and can then supply medical gas to the patient only when the housing is closed (Fig. 2, col.2 ll.17-44).

As for claim 66, Fields *et al.* is said to disclose gas delivery means (needle 34) in the upper portion of the housing to deliver the medical gas to the patient supply means (col.1 ll.35-42).

As for claim 67, Fields *et al.* is said to disclose the upper portion of the housing also including gas control means (spring 44) to control delivery of the gas to the patient supply means (col.2 ll.45-55).

As for claims 68 and 71, Fields *et al.* is said to disclose that the gas delivery means including a blender chamber (chamber 90) to receive the medical gas from the cartridge at a predetermined pressure and flow rate and gas control means (spring 44).

As for claim 154, the Examiner essentially repeats the position stated with respect to the elements in claim 59.

With respect to claim 155, reference is made to claim 67. With respect to claims 156 and 159, reference is made to claims 68 and 71.

In response to applicant's prior arguments, while the Examiner appears to agree with applicant's argument that Fields *et al.* does not teach that container 60 is contained within a closed housing, it is then stated that this limitation is not required by claim 59, 61-75, and 154-163. As for applicant's contention that Fields does not teach gas delivery means in the upper portion of the housing, the Examiner disagrees and states that Fields *et al.* teaches a needle 34 in the upper portion of the housing which delivers the medical gas to the nozzle 100 where the release of the gas is controlled by the user compressing a spring 44 via arms 45 (col.1 ll.35-42).

Finally, in response to applicant's arguments that Fields *et al.* does not teach apparatus capable of the most preferred use of applicant's invention, the Examiner contends that the features relied on are not cited in the rejected claims. Although the claims are said to be interpreted in light of the specification, limitations from the specification are said not to be read into the claims, citing *In re Van Geuns*, 988 F.2d 1181, 26 U.S.P.Q.2d 1957 (Fed. Cir. 1993). This rejection

is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Reference is initially made to the above-noted amendments to claims 59 and 154 in which the nature and substance of the present invention has been further clarified. Firstly, the claims specifically require a housing with upper and lower portions which can be connected such that the housing comprises a completely enclosed configuration. These claims also require that the compressed gas cartridge have a size and configuration such that when the housing is in its completely enclosed configuration the cartridge is contained entirely within the housing. Thus, irrespective of the fact that the Examiner has not explained on what basis it is contended that prior claim 59 did not require that the container be contained within a closed housing, it is respectfully submitted that this fact is now clear beyond question with respect to claims 59 and 154, and indeed with respect to the other claims in this application.

The Fields *et al.* reference is directed to relatively small containers for high pressure gasses such as Freon, to be released from a valve assembly as desired. Thus, upon attachment of valve head 10 containing valve housing 30 within sleeve 50, the device is ready for use. Such use merely requires inserting the container 60 into sleeve 50 as indicated by the dotted lines shown in Figure 2. As is stated in the specification of the Fields *et al.* patent, assembly requires placing the housing 30 inside the head 10, and the housing is then retained in place by the sleeve 50 which is screwed into place by engaging threads 52 with corresponding threads 24.

The container 60 is then slipped into the open ended sleeve 50 and pushed onto the needle, so that the needle pierces the diaphragm of the container 60. As is further stated therein, the device is configured so that the needle is not far

enough through the diaphragm to allow the hole 38 in the needle to communicate with the interior of container 60. It is thus specifically stated that in order to release the gas, the container 60 must be manually pushed further into the sleeve, causing the disc 40 to slide inwardly in the housing, and compressing the spring 44. This is shown by the dotted line configuration in Figure 2. Immediately upon releasing such manual pressure against the container 60, the spring 44 will push the disc 40 back to its original position, and no more flow of gas will be realized. It is thus clear that the flow of gas is maintained for only an extremely short maximum period of time defined by the minor amount of gas therein, and even more significantly, within that short period one must continuously press against the bottom of the container 60 at 62 in order to maintain even that small flow of gas.

It is also clear that the container 60 in Fields *et al.* is not contained within a closed housing, and certainly not as required by claims 59 and 154. Indeed, it is essential that the housing not be closed in Fields *et al.*, and that access to the container 60 be maintained in order for this device to operate in the first instance. This is completely contrary to the presently claimed invention, in which it is required that the compressed gas cartridge be fully contained within the housing, and not be accessible from the outside. The device itself will not operate, in fact, until this is the case, and the cartridge is fully contained therewithin. Indeed, the fact that claim 164 was not rejected on the basis of Fields *et al.* strongly suggests that the Examiner concurs with this analysis.

It is next noted that Fields *et al.* makes no reference whatsoever to the elements of claims 66-68 and 71 hereof. The Fields *et al.* device does not include the required gas delivery means in the upper portion of the housing for delivering the medical gas to the patient supply means, and certainly not the

gas control means to control the delivery of gas, nor the blender chamber of claim 68. Indeed, in prior art such as Fields *et al.*, the gas is directly released through nozzle 100, and it is therefore impossible to control the release of the gas once it exits from the cylinder itself. The overall concept of the present invention is thus entirely different from that of the prior art, such as Fields *et al.* Reference is made in this regard to the figures in this application, including Figures 2-8 hereof, which show the closed housing in conjunction with the gas delivery means of the present invention for accomplishing these purposes, including careful control of the various gas flows attainable therewith.

It is finally noted that, in addition to all of the above, the apparatus in Fields *et al.* could not possibly be used for the most critical purposes of the present invention. Fields *et al.* could not be utilized with a gas container which can supply the preferred gas compositions of the present invention for from three to six minutes of continuous breathing. To the contrary, Fields *et al.* is directed to small, short bursts of gas, as used, for example, with a nasal inhaler device, from a cartridge which is described in column 3 of the specification as being one that is about 2.5 inches long and about .75 inches in diameter. This, in fact, is a common cartridge, generally used with carbon dioxide gas, having about a 10 ml. water volume, as compared to the far higher volumes required to meet the most preferred embodiments of the present invention.

It is next noted that all of the claims in this application are directed to the administration of a medical gas, and specific such gases are disclosed in the specification. Fields *et al.* is not designed for such purposes; *i.e.* no "medical gases" are disclosed for use therein. As is stated in Fields *et al.*, a specified container and control valve assembly "has been found satisfactory for supplying the gas necessary to

operate medicinal sprayers, atomizers, and like devices." (Col.3 ll.16-18.) Thus, Fields *et al.* utilizes a gas only as a source of pressure to deliver a drug, presumably in either a liquid or powder form. In the present invention, however, the medical gas itself is the therapeutic entity which is supplied by this apparatus. Indeed, the gases employed by Fields *et al.* are exemplified only by Freon gas, which is certainly not a "medical gas" and has no known medical therapeutic effect in and of itself.

Use of gases such as Freon is also problematic since Fields *et seq.* refers to a container of a size indicated for holding about 2 liters of Freon gas measured at atmospheric pressure, which is said to be sufficient pressure for two or three applications of a nose sprayer. This is certainly not comparable to the types of medical gases under pressure in accordance with the present invention, in which cryogenic liquids such as N_2O and CO_2 under pressure are used for inhalation therapy in far different amounts from that of Fields *et al.*

Applicant would conclude by repeating the unassailable fact that Fields *et al.* does not in any way make reference to a container within an enclosed housing. To the contrary, as can be see in Fig. 2 of Fields *et al.*, part of the container itself is exposed, and projects from the housing referred to by the Examiner. This in itself would represent a safety hazard during use, due to rapid venting of the cartridge which would lead to dramatic temperature drops. The metal surface of the cartridge could then cause serious problems, such as upon exposure to bare skin and the like. All of this is quite apart from the fact that applicant's claims are also specifically directed to the significant safety device represented by the claimed first acceptance means associated with the housing, and second acceptance means associated with the cassette so that the proper

cassette containing the proper cartridge, and thus the proper medical gas, and only that medical gas, can be used in connection with the particular housing in question, in which these acceptance means are compatible with each other. If they are incompatible, the housing will not close, and the gas cannot be applied to the patient. None of this is even suggested by Fields *et al.* The Examiner's reference to rubber washer 26 and flange 48 does not represent acceptance means in accordance with the present claims, which could or could not be accepted; *i.e.*, they have no function in Fields *et al.* nor any relationship to whether or not the apparatus can actually deliver the appropriate medical gas. They are merely parts of the apparatus itself. Withdrawal of this rejection is therefore respectfully solicited.

Claim 164 has been rejected as being unpatentable over Pitesky *et al.* under 35 U.S.C. § 102(b). The Examiner contends that Pitesky *et al.* discloses apparatus for administering a medical gas comprising a housing with an upper portion (head C) connectable with a lower portion (housing D) in a configuration in which the housing is completely closed (Fig. 2), and compressed gas cartridge E disposed within the housing and containing a predetermined amount of medical gas sufficient for normal respiration (col.1 ll.58-60) and patient supply means (mouthpiece B) to provide the medical gas to the patient (Fig. 1, col.2 ll.12-15) in which the compressed gas cartridge is fully enclosed within the housing whereby access to the cartridge is prevented (Fig. 2, col.3 ll.38-40). This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Turning to the Pitesky *et al.* reference itself, there is disclosed a rather simple portable hyperventilation device for the delivery of carbon dioxide from a carbon dioxide cartridge E shown therein. In this device the cartridge is

placed in elongate cup-shaped housing D, which is then screwed onto the base of head C. By doing so, the upper end of the cartridge is pierced by longitudinally apertured prong F. Control of the gas into the inhaler tube or mouthpiece B is then either in an on or off position by means of the rotation of valve K. Thus, the system is either in the position shown in Fig. 2 where the gas is retained within the cartridge E, or rotation of the valve K permits the gas to exit from orifice 12 through passage means 14 into bore 60 and thus into mouthpiece B for use by the patient in the configuration shown in Fig. 3. This can be contrasted to the device set forth in amended claim 164, in which the selected medical gas of the present invention can be released from the claimed compressed gas cartridge hereof without necessarily being released directly to the patient. Claim 164 now specifically requires gas delivery means which includes a blender chamber in which one or more gases are maintained at reduced pressures, but not necessarily supplied to the patient until actuation of the required demand valve by inhalation by the patients themselves. This then results in supply of the predetermined amount of the medical gas in question from the blender chamber to the patient, but only when the demand valve has been actuated. It is therefore clear that amended claim 164 clearly and patentably distinguishes over Pitesky *et al.*

Claims 61 and 62 have been rejected as being unpatentable over Fields *et al.* in view of Ritson *et al.* under 35 U.S.C. § 103(a). After admitting that Fields *et al.* does not teach that the first acceptance means and the second acceptance means comprise a plurality of corresponding key means consisting of male and female members, Ritson *et al.* is cited as disclosing a medication delivery system with a housing (body 2) and a cassette (housing 40), a compressed gas cartridge (canister 30) mounted on a cassette, patient supply means (mouthpiece 20) and

mounting means including a plurality of first acceptance means (key plate 440) compatible with a plurality of second acceptance means (protrusions 48) on the cassette in the form of male and female members for mounting the cassette within the housing (Figs. 3-9, col.11 ll.52-63). The Examiner thus concludes that it would be obvious to modify the first and second acceptance means of the apparatus in Fields *et al.* to include key means consisting of corresponding male and female members as taught by Ritson *et al.* to prevent insertion of the wrong or unauthorized medication into the housing. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Applicant initially reiterates all of the above-noted contentions with respect to the clear deficiencies of Fields *et al.*

Turning to the Ritson *et al.* reference, like the case in Fields *et al.*, neither of these references is directed to the subject matter of the present invention; namely, the delivery of a predetermined dosage of a medical gas. In both of these cases the patentees are concerned with gases only as delivery vehicles, and not medical gases. These gases are merely present to assist in delivering a liquid or powder drug therewith. This difference becomes of considerable significance when the overall nature and structure of the present invention is compared and contrasted to those in these references. Thus, the highly complex electronic components used by Ritson *et al.* include many functions which are entirely inapplicable and/or unnecessary in connection with the present invention. These include specifically calibrated orifices for determining the inhalation flow rate range and the exhalation flow rate range over a selected number of known flow rates for operation of the Ritson *et al.* device in the first instance.

Putting all of this aside, however, one critical element is missing from these references. The simplified mechanical first and second acceptance means of the present invention as required by claims 61 and 62 are specifically adapted so that these preferably male and female members must mate in order for the housing in the present invention to be fully closed. If they do not mate, or are incompatible, placement of applicant's compressed gas cartridge within the completely enclosed structure of the present invention becomes impossible, and this in turn entirely prevents the patient from actually using the device and/or obtaining the medical gas thereof in the first instance. On the other hand, in Ritson *et al.*, while the complex electronic multi-bit system thereof may ultimately prevent use of the device, it does not prevent the canister 30 itself from being enclosed within housing 40 either within or without the durable body 2 thereof. Again, the far simpler mechanical mechanism required by the present claims includes the first and second acceptance means which, if incompatible, prevents the claimed compressed gas cartridge from being enclosed within a housing in the first instance, and that fact alone prevents it from being used by the patient in an improper manner. This simple and elegant safety mechanism is far different from anything disclosed in Ritson *et al.*, irrespective of the varying environments of Ritson *et al.* and Fields *et al.* compared to that of the present invention.

It is therefore respectfully submitted that claims 61 and 62 in their present form clearly and patentably define over this combination of references, and withdrawal of this rejection is also respectfully requested.

Claim 63 has been rejected as being unpatentable over Fields *et al.* in view of Ziherl *et al.* under 35 U.S.C. § 103(a). After admitting that Fields *et al.* fails to teach a plurality of compressed gas cartridges containing a plurality of medical

gases, Ziherl is said to disclose a portable inhaler with a housing A and a plurality of compressed gas cartridges 46 and 49 containing a plurality of medical gases (Figs. 1-4; col.2 ll.47-49; col.3 ll.12-13, 38-39, 42-44, and 50-52; col.6 ll.52-72). The Examiner concludes that it would be obvious to modify Fields *et al.* to further comprise a plurality of compressed gas cartridges as taught by Ziherl *et al.* to provide a mixture of medical gases simultaneously. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Applicant reiterates all of his above-noted contentions with respect to the clear deficiencies of Fields *et al.* with respect to claim 59, and thus also with respect to claim 63. As for Ziherl *et al.*, it is apparent that this reference has been applied solely because it includes more than one gas cylinder, particularly since in all other respects it is essentially irrelevant to the presently claimed invention. Ziherl *et al.* is thus inapplicable even to the disclosure of Fields *et al.*, much less to that of the presently claimed invention. In Ziherl *et al.*, a portable anesthesia machine, oxygen inhalator or resuscitator is disclosed in which two different cylinders, 46 and 49, containing gases (in this case, oxygen on the one hand and a mixture of helium and cyclopropane on the other) which can be screwed into separate sides of the body member 1. In this manner, these gases can ultimately be injected into passageway 4 for entry into rebreathing bag 117. When desired for use, mask E is placed over the patient's face, and the anesthetist can then use ring 92 to uncover openings 91 and permit the gas to pass through the sodium-lime canister assembly for the removal of carbon dioxide, and then to the patient.

It is thus initially noted that Ziherl *et al.* clearly does not overcome any of the specific deficiencies of Fields

et al. discussed above with respect to claim 59. Secondly, the two canisters 46 and 49 used in Ziherl *et al.* are not even contained in the same housing, and they certainly are not directed to a single dose of medical gases which are applicable to a patient in accordance with the present invention. Again, neither of these references is even intended to supply a single dose of a medical gas to a patient in a controlled environment, which is both safe and simple to use. In summation, it is again specifically noted that each of the above-discussed limitations of claim 59 providing for the safety factors inherent in the presently claimed invention are certainly not overcome or suggested by the addition of Ziherl *et al.* to Fields *et al.*, even if this combination were legitimate in the first place. Therefore, reconsideration and allowance of claim 63 is also respectfully requested.

Claims 64 and 65 have been rejected as being unpatentable over Fields *et al.* in view of Ziherl *et al.* and further in view of Ritson *et al.* under 35 U.S.C. § 103(a). After admitting that the combination of Fields *et al.* and Ziherl *et al.* fails to teach that the acceptance means comprise a plurality of corresponding key means consisting of male and female members, the Examiner relies upon Ritson *et al.* for the reasons previously stated. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Applicant reiterates all of his above-noted contentions with respect to the clear deficiencies of each of these references as applied by the Examiner. It is thus submitted that each of the above arguments also clearly applies with at least equal force to claims 63 and 64, and that further detailed analysis of each of these three references, and a repeat of all of applicant's previously presented arguments with respect to their failure to teach the specific claim limitations

in question is unnecessary at this time. It is thus submitted that these claims are also clearly patentable over the art.

Claims 69, 72, 74, 157, 160, and 162 have been rejected as being unpatentable over Fields *et al.* in view of Psaros. After admitting that Fields *et al.* fails to teach that the gas control means comprises a gas control sensor to sense the content and pressure of the medical gas, and valve means to terminate supply of the medical gas based on the sensed content and pressure of the medical gas, Psaros is relied upon for these limitations. This reference is said to disclose a portable anesthetic machine 38 comprising a compressed gas cartridge (gas cylinder 18) containing a medical gas, a gas control sensor (gas analyzer 22) for measuring the gas concentration, a control unit 38 for controlling a control valve 40 and dispensing of medical gas to the user based on the measurements of the gas control sensor, and pressure gauges 42 and 44 to supply the control unit with pressure information (col.3 ll.9-20 and 36-34). The Examiner thus concludes that it would be obvious to modify Fields *et al.* to further comprise a gas control sensor and pressure gauges as taught by Psaros to ensure correct gas dosages delivered to the patient at the correct pressure. It is also said to be obvious that the user could set the control unit to terminate supply of the gas based on the sensed content and pressure to prevent incorrect dosages.

As for claims 74 and 162, after admitting that Fields *et al.* and Psaros fail to teach a second gas control means for sensing the pressure leaving the blender chamber, the Examiner concludes that it would be obvious to modify the apparatus taught by this combination of references to have a second gas control means such as a pressure gauge as taught by Psaros to sense pressure leaving the blender chamber to ensure that the gas is delivered at the correct pressure. It is further said to be mere duplication of the essential working parts of the device

involving only routine skill in the art. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Applicant would first reiterate all of his above-noted contentions with respect to the clear deficiencies of Fields *et al.*, particularly with respect to claims 59 and 154. It is again noted that Psaros does not even overcome these clear patentable distinctions, much less the additional limitations set forth in the dependent claims now referred to by the Examiner.

Turning to Psaros, this patent is directed to a portable anesthetic machine 2 generally used to anesthetize patients prior to surgery. Thus, the invention of this patent is said to improve upon such apparatus in terms of safety and reliability, and without the need to interrupt respiratory assistance. The apparatus includes a gas flow generator to generate a continuous flow of gas at adjustable pressures and flow rates, and a membrane disposed in the gas flow pathway made of self-sealing material so that specified amounts of liquid anesthetic can be dispensed into the gas flow pathway a number of times. As is thus shown in Fig. 1 thereof, the gas flow generator 4 creates a flow of ambient air into inspiratory line 6 to the patient. Liquid anesthetic that is a volatile substance is injected with syringe 12A through membrane 10 so that it vaporizes and is carried by this breathing gas to the patient. The apparatus also includes control unit 16 to set various respiratory parameters, and to control the gas flow generator, as well as additive gas from gas cylinder 18, such as oxygen or nitric oxide. The gas analyzer 22 collects the gas samples for control of the respirator on the basis of gas concentrations.

It is noted that the present invention is not a method which employs an anesthesia device such as that in Psaros.

Thus, while the short duration application of the present method can result in mild but conscious sedation and pain reduction, it does not result in anesthesia or unconsciousness, as is the case with Psaros. This also demonstrates that there is little incentive to even combine Psaros with Fields *et al.* in the first instance. Any basis for combining the control system of Psaros with the dispenser in Fields *et al.* appears to be based solely upon hindsight reconstruction since it would be difficult, if not impossible, to even make such a combination in the first instance.

Indeed, the gas analyzers employed by Psaros are necessary in that portable anesthetic machine which is operating continuously with changing gas amounts and concentrations. In the present invention, the nature and amount of the gas is completely controlled by the single dose of medical gas contained in the compressed gas cartridges themselves. In the case of the present invention in which a number of such cartridges are employed with a blender chamber, the fixed pressure of the gas and the variable valves used to control gas flow into the blending chamber, accomplish this result. Gas blending is thus controlled mechanically based on the pressure and density of the gas emptying from the cylinders into the blending chamber. Thus, the only gas which may be analyzed in accordance with the present invention would be the oxygen content thereof. No sensor controls the rate of flow or amount of gas delivered to the patient in accordance with the present invention. The environments of these inventions are so different as to render it almost incredible to try to reconstitute this combination of references to somehow provide the claimed invention hereof. The removal of this rejection is therefore respectfully requested.

Claims 70, 73, 75, 158, 161, and 163 have been rejected as being unpatentable over Fields *et al.* in view of

Psaros and further in view of Landis *et al.* under 35 U.S.C. § 103(a). After admitting that the combination of Fields *et al.* and Psaros does not teach room air breathing means such that upon terminating supply of the medical gas the room air breathing means supplies room air to the patient, Landis is said to disclose an inhalation device with a housing 10, compressed air cartridge 94 within the housing, patient supply means (mouthpiece 16), and room air breathing means (intake opening 70) to supply room air to the patient (Figs. 1-4, col.4 ll.4-6). The Examiner thus concludes that it would be obvious to modify the combined apparatus of Fields *et al.* and Psaros to further comprise room air breathing means as taught by Landis so that the patient may breathe ambient air when the control unit terminates the supply of medical gas in order to maintain sufficient oxygen levels.

As for claims 75 and 163, after admitting that the combination of Fields *et al.* and Psaros fails to teach the gas control means comprising an air inlet port to permit air to enter the housing and an air intake valve to control entry of the air when the valve means terminates supply of the medical gas, it is said to be obvious to modify the combination of Fields *et al.* and Psaros to further comprise an air inlet port as taught by Landis. It is again noted that the combination of each of these references does not expressly teach an air intake valve to control the entry of air, but Psaros is said to teach use of an expiratory valve 26 to control flow through the expiratory line 8. It is thus said to be obvious to modify the apparatus of the combination of these three references to further include an air intake valve, since it is said to be mere duplication of the essential working parts of the device requiring only routine skill. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Applicant would reiterate all of his above-noted contentions with respect to the clear deficiency of both Fields *et al.* and Psaros with respect to all of the pending claims, and particularly the arguments set forth above with respect to claims 59 and 154. Clearly the addition of Landis does not overcome any of these deficiencies, nor was the Examiner's citation of Landis intended to overcome these deficiencies. On that basis alone, it is clear that these claims are patentable over the art, and reconsideration of this rejection is respectfully requested.

As for the Examiner's arguments regarding this three-way combination, the additional limitations in the dependent claims to which this rejection is directed relate to room air breathing means such that upon termination of the supply of medical gas the room air breathing means can supply air so that the patient can breathe. This is a safety mechanism intended for use with the medical gases of the present invention. No such safety mechanism is included in Landis.

Turning to Landis itself, this rather fundamental structure for a breath-activated medication spray is relied upon by the Examiner primarily for the use of intake opening 70 in conduit 68 therein. This is a mechanism by which the user can directly inhale atmospheric air through the mouthpiece 16. This, in turn, actually activates a series of steps culminating in a predetermined metered amount of medicament stored in cartridge 94 being injected into this air stream being breathed by the patient. Thus, the breathing mechanism in Landis, far from constituting room air breathing means which upon termination of a supply of medical gas supplies air for breathing by the patient, is instead required to be breathed by the patient in order to actuate the medicaments in Landis. These are entirely opposite in function, way and result. Thus, operation of the device in Landis is initiated by the patient's

inhalation, which in turn creates an airflow against door means 54 causing magnet 56 to disengage and rotate, coming into proximity with switch means 64, thus causing the contacts of the switch to close and activate solenoid 66 which in turn permits spring means 52 to be disengaged, forcing the cartridge downwardly so as to release medicament as shown in Fig. 4 thereof. Nothing which is anything like this occurs in the present invention, and these claims are not directed to any such apparatus. Thus, the addition of Landis adds nothing to Fields *et al.* and Psaros with respect to these limitations.

Similarly, with respect to claims such as claims 75 and 163, the required air inlet port and air intake valve are said to control entry of air for delivery to the patient supply means only when the valve means terminates supply of the medical gas. Again, this is exactly contrary to what is taught in Landis. Therefore, reconsideration and removal of this rejection is respectfully requested.

Claims 165-167 have been rejected as being unpatentable over Pitesky in view of Ritson *et al.* under 35 U.S.C. § 103(a). After admitting that Pitesky fails to teach a cassette on which the gas cartridge is mounted and mounting means for mounting the cassette within a housing, Ritson *et al.* is relied upon. The Examiner repeats the above-noted contentions with respect to the disclosure of Ritson *et al.* that the first acceptance means (key plate 440) compatible with a plurality of second acceptance means (protrusions 48) in the form of male and female members for mounting the cassette within the housing. The Examiner thus concludes that it would be obvious to modify Pitesky to include a cassette on which the compressed gas cartridge is mounted with the required acceptance means thereupon. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Applicant reiterates all of his above-noted contentions with respect to the clear deficiencies of both Pitesky and Ritson *et al*. Applicant has, in fact, specifically set forth above clear distinctions between claim 164 and Pitesky. It is clear that Ritson *et al*. does not overcome these differences, and in fact the Examiner's position with respect to Ritson *et al*. does not even allege that this is the case. Thus, on this basis alone, it is clear that these claims are fully patentable over the art. Certainly Ritson *et al*. does not include the required gas delivery means including the blender chamber and demand valves required by these claims. Therefore, reconsideration and removal of this rejection is also respectfully requested.

Finally, claims 1-26 have been rejected on the basis that claims 1-26 of the present application conflict with claims 1-26 of Application No. 11/599,582. The Examiner requests that a line of demarcation be maintained between these two applications. Applicant fully intends to do so, and that in any event since neither of these applications has been found to be allowable, applicant submits that this rejection will ultimately be rendered moot in view of the prosecution of these respective applications.

It is therefore respectfully submitted that all of the claims in this application now possess the requisite novelty, utility and unobviousness to warrant their immediate allowance, which action is therefore respectfully solicited. If, however, for any reason the Examiner does not believe that such action can be taken, it is respectfully requested that she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections to the allowance of these claims.

Finally, if there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: March 20, 2009

Respectfully submitted,

By 

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